

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

**ARROW SIMVASTATIN 10, (film-coated tablets)**

**ARROW SIMVASTATIN 20, (film-coated tablets)**

**ARROW SIMVASTATIN 40, (film-coated tablets)**

**ARROW SIMVASTATIN 10 mg** contains 73.43 mg lactose monohydrate

**ARROW SIMVASTATIN 20 mg** contains 146.86 mg lactose monohydrate

**ARROW SIMVASTATIN 40 mg** contains 293.72 mg lactose monohydrate

Read all of this leaflet carefully before you start taking **ARROW SIMVASTATIN**.

- Keep this leaflet. You may need read it again.
- If you have further question, please ask your doctor or your pharmacist.
- **ARROW SIMVASTATIN** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### What is in this leaflet

1. What **ARROW SIMVASTATIN** is and what it is used for.
2. What you need to know before you take/ use **ARROW SIMVASTATIN**.
3. How to take /use **ARROW SIMVASTATIN**.
4. Possible side effects.
5. How to store **ARROW SIMVASTATIN**.
6. Contents of the pack and other information.

#### 1. What **ARROW SIMVASTATIN** is and what it is used for

**ARROW SIMVASTATIN** tablets belongs to a group of medicines called Serum-cholesterol reducers.

**ARROW SIMVASTATIN**, in combination with diet, is used to lower levels of cholesterol and other fats in the blood in patients with:

- primary or hereditary high cholesterol
- mixed high cholesterol, when diet is not sufficient to lower cholesterol
- heart disease and high cholesterol and not responding to change in diet to:
- reduce the risk of death
- reduce the risk of heart attack
- reduce the risk of receiving surgery such as a bypass
- slow the progression of heart disease

## 2. What you need to know before you take ARROW SIMVASTATIN

### Do not take ARROW SIMVASTATIN

- if you are hypersensitive (allergic) to Simvastatin or any of the other ingredients of Arrow Simvastatin.
- If you are unsure about this, ask your doctor (see section 6. Contents of the pack and other information)
- Are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding and fertility)
- have acute or chronic liver problems
- have a condition called porphyria
- unexplained persistent elevation of serum transaminase (liver enzymes)
- If you are taking medicine(s) with one or more than one of the following active ingredients:
  - Itraconazole, ketoconazole, posaconazole, or voriconazole (used to treat fungal infections),
  - HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (HIV protease inhibitors are used for HIV infections),
  - boceprevir or telaprevir (used to treat hepatitis C virus infection),
  - erythromycin, clarithromycin, or telithromycin (used to treat infections),
  - nefazodone (used to treat depression),
  - cobicistat (used to treat HIV infection),
  - gemfibrozil (used to lower cholesterol),
  - cyclosporin (used in organ transplant patients),
  - danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus),
  - lomitapide (used to lower familial cholesterol).
- If you have porphyria

### **Warnings and precautions**

**Take special care with ARROW SIMVASTATIN:**

- If you have any kidney disorder, do not take **ARROW SIMVASTATIN** without consulting your doctor first
- If you are taking any of the following medicines:
  - ciclosporin
  - itraconazole and ketoconazole used to treat fungal infections
  - niacin, also known as vitamin B<sub>3</sub>
  - antibiotics such as erythromycin and clarithromycin
  - nefazodone, an anti-depressant
  - HIV medicine
  - medicine called fibric acid derivatives, used to lower cholesterol
  - if you drink large amounts of alcohol (or have a history of liver disease)
- If you have severe infection, as the use of **ARROW SIMVASTATIN** may lead to kidney failure or a condition called rhabdomyolysis (the breakdown of muscle fibers)
- ever had liver disease - your doctor may want to check your liver function before and during treatment with **ARROW SIMVASTATIN**
- if you have a condition associated with muscle pain or weak muscles

Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness while on **ARROW SIMVASTATIN** treatment. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage.

The risk of muscle breakdown is greater at higher doses of **ARROW SIMVASTATIN**, particularly the 80 mg dose. The risk of muscle breakdown is also greater in certain patients. Talk with your doctor if any of the following applies:

- if you are older than 65 years,
- if you are female,
- if you have kidney problems,
- if you have uncontrolled hypothyroidism,
- if you have a personal or family history of muscle disorders,
- if you previously experienced muscle disorders with statin or fibrate use,
- if you consume large amounts of alcohol

#### **Children and adolescents**

The safety of **ARROW SIMVASTATIN** has not been determined in children under the age of 12 years and should therefore not be given to children.

#### **Other medicines and **ARROW SIMVASTATIN**:**

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Some of the medicines that may interact with **ARROW SIMVASTATIN** and increase the risk of myopathy (muscle weakness) and kidney failure are:

- Antifungal medicines e.g. itraconazole or ketoconazole, fluconazole, posaconazole, or voriconazole (for fungal infections)
- Ciclosporin (used in organ transplant patients)
- Niacin (medicine for lowering cholesterol) (a form of vitamin. If you are Asian you should not use ARROW SIMVASTATIN with niacin)
- Antibiotics such as erythromycin ~~and~~, clarithromycin or telithromycin (used for bacterial infections)
- HIV protease inhibitors such as nelfinavir, ritonavir, and saquinavir (used in the treatment of HIV)
- hepatitis C antiviral agents such as boceprevir, telaprevir, elbasvir or grazoprevir (used to treat hepatitis C virus infection),
- Nefadazone (a medicine for depression)
- medicines with the active ingredient cobicicstat (used to treat HIV infection),
- danazol (a man-made hormone use to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus)
- amiodarone (used to treat irregular heartbeat),
- verapamil, diltiazem, or amlodipine (used to treat high blood pressure, chest pain associated with heart disease, or other conditions.
- lomitapide (used to treat a serious and rare genetic cholesterol condition),
- daptomycin (a drug used to treat complicated skin and skin structure infections and bacteraemia). It is possible that side effects affecting the muscles may be higher when this medicine is taken during treatment with simvastatin (e.g. ARROW SIMVASTATIN). Your doctor may decide that you stop taking ARROW SIMVASTATIN for a while.
- ticagrelor (antiplatelet medicine)
- colchicine (ani-gout medicine),
- rifampicin (medicine used to treat tuberculosis),
- warfarin, used to prevent the clotting of blood
- digoxin (medicine to treat various heart conditions)
- cholestyramine (medicine used to lower cholesterol)
- fibrates with an active ingredient like gemfibrozil and bezafibrate (used to lower cholesterol),
- If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart ARROW SIMVASTATIN. Taking ARROW SIMVASTATIN with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis).

#### **ARROW SIMVASTATIN with food and drink and alcohol**

**ARROW SIMVASTATIN** tablets are taken orally, with or without food. Tablets are swallowed whole with a little liquid before or after the meal. Avoid grapefruit juice during treatment with **ARROW SIMVASTATIN**

#### **Pregnancy and breastfeeding and fertility**

You should not take ARROW SIMVASTATIN if you are pregnant or breastfeeding.

If are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or healthcare professional for advice before taking **ARROW SIMVASTATIN**.

#### **Driving and using machinery:**

**ARROW SIMVASTATIN** may cause dizziness. You should not drive or use machinery until you are sure that your ability to do such activities is not affected by **ARROW SIMVASTATIN**.

#### **Important information about some of the ingredients of ARROW SIMVASTATIN:**

**ARROW SIMVASTATIN** contains lactose monohydrate.

ARROW SIMVASTATIN contains lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Contains lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take ARROW SIMVASTATIN.

### 3. How to take ARROW SIMVASTATIN:

Do not share medicines prescribed for you with any other person.

Always take Arrow Simvastatin exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Follow the diet the doctor gave you carefully. This is the most important part of controlling your condition, and is necessary if the medicine is to work properly.

Always take **ARROW SIMVASTATIN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is 10 mg a day in the evening to a maximum of 80 mg once a day in the evening. Your doctor will decide on the dosage based on your condition.

Your doctor will tell you how long your treatment with ARROW SIMVASTATIN will last.

If you have the impression that the effect of ARROW SIMVASTATIN is too strong or too weak, tell your doctor or pharmacist.

Your doctor may also prescribe **ARROW SIMVASTATIN** together with cholestyramine. In this case **ARROW SIMVASTATIN** must be taken 1 hour before, or 4 hours after taking cholestyramine.

#### **If you take more ARROW SIMVASTATIN than you should:**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Do not forget to take the product pack with you, as well as the remaining tablets.

#### **If you forget to take/missed a dose of ARROW SIMVASTATIN:**

If you miss a dose of **ARROW SIMVASTATIN**, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

### 4. Possible side effects

**ARROW SIMVASTATIN** can have side effects.

Not all side effects reported for **ARROW SIMVASTATIN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care professional for advice.

If any of the following happens, stop taking ARROW SIMVASTATIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- hypersensitivity (allergic) reactions including swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat which may cause difficulty in breathing
- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ARROW SIMVASTATIN**.

You may need urgent medical attention or hospitalisation.

#### **Tell your doctor if you notice any of the following:**

The following side effects have been reported frequently:

- nausea
- vomiting
- feeling bloated
- flatulence
- dyspepsia (indigestion)
- abdominal pain/cramps
- tingling feeling or numbness of the skin
- hair loss
- myalgia
- muscle cramps

The following side effects have been reported less frequently:

- constipation
- diarrhoea
- inflammation of pancreas
- anaemia (low red blood cell count)
- Neutropenia
- Thrombocytopenia
- Increased erythrocyte sedimentation rate
- Eosinophilia
- inflamed blood vessels, also called vasculitis
- raised sugar levels
- weight gain
- headache
- dizziness
- feeling tired
- paraesthesia
- Peripheral neuropathy

- memory loss, forgetfulness, sleeplessness and confusion
- photosensitivity
- vision blurred
- vision impairment
- hypersensitivity pneumonitis
- Skin rash
- Alopecia
- Urticaria
- Pruritis
- Lichenoid drug eruptions
- Myopathy
- Myositis
- Rhabdomyolysis
- Polymyalgia
- Rheumatica
- Arthritis
- Arthralgia
- Muscle rupture
- Fever, flushing
- Feeling weak
- Asthenia
- Hepatitis/jaundice
- Fatal and non-fatal hepatic failure
- Gynecomastia
- Increase in serum transaminases
- Elevated alkaline phosphatase
- Increase in serum CK levels

The following side effects have been reported but the frequency is unknown:

- Interstitial lung disease
- Tendinopathy
- Mass gain
- Depression
- Erectile dysfunction

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/>. By reporting side effects, you can help provide more information on the safety of ARROW SIMVASTATIN.

### **5. How to store ARROW SIMVASTATIN**

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN

Store in the original packaging at or below 25 °C. Protect from light.

Store in the original package/container.

Keep the blister packs in the outer carton until required for use.

Do not store in the bathroom.

Do not use after the expiry date stated on the carton.

Return any expired or unused medicine to your pharmacist for safe disposal.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### **6. Contents of the pack and other information**

**What ARROW SIMVASTATIN contains:**

- The active substance is Simvastatin

**ARROW SIMVASTATIN 10:** each tablet contains 10 mg simvastatin as the active ingredient.

**ARROW SIMVASTATIN 20:** each tablet contains 20 mg simvastatin as the active ingredient.

**ARROW SIMVASTATIN 40:** each tablet contains 40 mg simvastatin as the active ingredient.

ARROW SIMVASTATIN contains lactose monohydrate.

- The other ingredients are

Ascorbic Acid

Butylated Hydroxyanisole

Citric Acid Monohydrate

Ethanol Anhydrous

Lactose Monohydrate

Magnesium Stearate

Microcrystalline Cellulose

Pregelatinized Starch

Talc

Opadry II Pink

#### **What ARROW SIMVASTATIN looks like and contents of the pack**

**ARROW SIMVASTIN 10:** Pink, shield shaped, film-coated tablet with "SV'10" on one side and "Arrow Logo" on the other.

**ARROW SIMVASTATIN 20:** Tan, shield shaped, film-coated tablet, with "SV 20" on one side and plain on the other.

**ARROW SIMVASTATIN 40:** Pink, shield shaped, film-coated tablet, with 'SV 40' on one side and "Arrow Logo" on the other.

**ARROW SIMVASTATIN 10:** PVDC coated PVC/PE laminate, with hard tempered aluminium foil, blister packs of 28 or 30 tablets.

**ARROW SIMVASTATIN 20:** PVDC coated PVC/PE laminate, with hard tempered aluminium foil, blister packs of 28 or 30 tablets.

**ARROW SIMVASTATIN 40:** PVDC coated PVC/PE laminate, with hard tempered aluminium foil, blister packs of 28 or 30 tablets.

#### **Holder of Certificate of Registration**

Astral Pharma (Pty) Ltd  
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#### **This leaflet was last revised in**

Date of registration: 07 April 2006

Date of revision of text: 02 September 2022

#### **Registration number**

**ARROW SIMVASTATIN 10:** A38/7.5/0707

**ARROW SIMVASTATIN 20:** A38/7.5/0708

**ARROW SIMVASTATIN 40:** A38/7.5/0709

#### **Access to the corresponding Professional Information**

Can be obtained on the SAHPRA website